

Claims

1. A composition for treating premature ejaculation by pulmonary inhalation, said composition comprising an antidepressant.
- 5 2. A composition as claimed in claim 1, wherein the antidepressant is a tricyclic antidepressant.
3. A composition as claimed in either of the preceding claim, wherein the
10 composition comprises two or more antidepressants.
4. A composition as claimed in any one of the preceding claims, wherein the composition comprises a further therapeutic agent, which is not an antidepressant.
- 15 5. A composition as claimed in claim 4, wherein the further therapeutic agent is also effective in treating PE.
6. A composition as claimed in claim 4 or claim 5, wherein the further
20 therapeutic agent is a benzodiazepine.
7. A composition as claimed in any one of the preceding claims, wherein the administration of the composition by pulmonary inhalation is not accompanied with the adverse side effects usually associated with the administration of the
25 antidepressant.
8. A composition as claimed in any one of the preceding claims, wherein the composition provides a dose of antidepressant of less than about 25mg, less than about 20mg, less than about 15mg, less than about 10mg, less than about 5mg, less than about 2mg or less than about 1mg.
- 30 9. A composition as claimed in any one of the preceding claims, wherein the composition provides an onset of the therapeutic effect within no more than 30 minutes, no more than 25 minutes, no more than 20 minutes, no more than 15

minutes, no more than 10 minutes, no more than 8 minutes, no more than 6 minutes, no more than 5, 4, 3 or 2 minutes, or no more than 1 minute, following pulmonary administration.

- 5 10. A composition as claimed in any one of the preceding claims, wherein the composition is a dry powder composition.
11. A composition as claimed in claim 10, wherein the composition comprises particles of antidepressant having a mass median aerodynamic diameter of about
10 10 μ m or less.
12. A composition as claimed in claim 11, wherein the mass median aerodynamic diameter is about 5 μ m or less.
- 15 13. A composition as claimed in any one of claims 10 to 12, wherein at least 90% of the antidepressant has a particle size of about 10 μ m or less.
14. A composition as claimed in claim 13, wherein at least 90% of the antidepressant has a particle size of about 5 μ m or less.
- 20 15. A composition as claimed in any one of claims 10 to 14, wherein the composition further comprises an additive material.
16. A composition as claimed in claim 15, wherein the additive material is
25 provided in an amount from about 0.15% to about 5% of the composition, by weight.
17. A composition as claimed in claim 15 or claim 16, wherein the additive material is selected from the group consisting of leucine, magnesium stearate,
30 lecithin, and sodium stearyl fumarate.
18. A composition as claimed in any one of claims 10 to 17, wherein the composition further comprises an excipient material.

19. A composition as claimed in claim 18, wherein the excipient material is in the form of carrier particles having an average particle size of about 40 to about 70 μ m.
- 5 20. A composition as claimed in any one of claims 1 to 9, wherein the composition comprises a solution pMDI formulation including a propellant, a solvent and water.
- 10 21. A composition as claimed in any one of claims 1 to 9, wherein the composition is a suspension pMDI formulation including a propellant.
22. A composition as claimed in claim 20 or claim 21, wherein the propellant is HFA134a and/or HFA227.
- 15 23. A method of treating premature ejaculation, the method comprising administering to a subject in need of such treatment a composition as claimed in any one of the preceding claims.
- 20 24. A method as claimed in claim 23, wherein the method does not cause the adverse side effects normally associated with the administration of the antidepressant.
- 25 25. Use of an antidepressant in the manufacture of a medicament for treating premature ejaculation by pulmonary inhalation, wherein the medicament comprises a composition as claimed in any one of claims 1 to 22.
- 30 26. A use as claimed in claim 25, wherein the medicament does not cause the adverse side effects normally associated with the administration of the antidepressant.
27. A dry powder inhaler device comprising a composition as claimed in any one of claims 1 to 22.

28. A dry powder inhaler device as claimed in claim 27, wherein the inhaler is an active inhaler.

5 29. A dry powder inhaler as claimed in claim 27 or 28, wherein the inhaler is a breath actuated inhaler device.

30. A blister for use in a dry powder inhaler device as claimed in any one of claims 27 to 29, wherein the blister contains the composition.

10

31. A composition as claimed in any of claims 1-22, a method as claimed in claim 23 or 24, a use as claimed in claim 25 or 26, an inhaler as claimed in any of claims 27-29, or a blister as claimed in claim 30, wherein the adverse side effects, if any, provoked by the administration of the composition by inhalation are such that
15 they would easily be tolerated by an average recipient.